PEARSON, J.

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

JANE OLSZESKI,)
Plaintiff,) CASE NO. 5:19CV1787
v.)) JUDGE BENITA Y. PEARSON
ETHICON WOMEN'S HEALTH AND UROLOGY, et al.,)))
Defendants.) <u>ORDER</u>) [Resolving ECF Nos. <u>127</u> , <u>138</u> , <u>139</u>]

Pending before the Court is (1) Defendants' Motions to Exclude the Expert Testimony of Jimmy Mays, Ph.D. (ECF No. 127), (2) Plaintiff's Motion to Exclude Certain General Expert Opinions and Testimony of Juan Carlos Felix, M.D. (ECF No. 138), and (3) Plaintiff's Motion to Exclude or Limit the General Opinions and Testimony of Salil Khandwala, M.D. (ECF No. 139). All three pending motions have been fully briefed. *See* ECF Nos. 144, 145, 152, 153, 182, 187, 190. For the reasons given below, each of the pending motions to exclude are denied.

I. Background

A. Defendants' Motions to Exclude the Expert Testimony of Jimmy Mays, Ph.D ("Dr. Mays") (ECF No. 127)

Defendants seek to exclude Dr. Mays' testimony because it is unreliable, irrelevant, and otherwise inadmissible as (1) Dr. Mays' opinions do not fit the facts of the case (ECF No. 127-1 at PageID #: 9555), (2) Dr. Mays' proposed alternatives were not technically or economically feasible, or safer, at the time of Plaintiff's surgery (*Id.* at PageID #: 9556 – 9559), and (3) Dr.

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Mays' opinions are unreliable and do not support his conclusion because they were not tested adequately (*Id.* at PageID #: 9556 – 9557, 9559 – 9567).

In opposition, Plaintiff argues that "Dr. Mays is a well-qualified professor of biomedical engineering, whose career has focused on polymer materials[,]" and "[h]is degradation and alternative design opinions are relevant to Plaintiff's product liability claims against Defendants and based upon a reliable methodology. Moreover, even if Defendants' criticisms against Dr. Mays's opinions were accurate – which they are not – such are merely grounds for cross-examination and not exclusion." ECF No. 153 at PageID #: 19756.

B. Plaintiff's Motion to Exclude Certain General Expert Opinions and Testimony of Juan Carlos Felix M.D. ("Dr. Felix") (ECF No. 138)

Plaintiff seeks to exclude Dr. Felix's testimony because it is not scientifically reliable, but instead amounts to nothing more than (1) *ipse dixit* testimony supported by insufficient review of scientific literature (ECF No. 138 at PageID #: 16078 – 16083, 16086 – 16088), and (2) "anecdotal evidence, improper extrapolation, speculation, and subjectivity" (ECF No. 138 at PageID #: 16083 – 16085). In opposition, Defendants argue "Dr. Felix's opinions serve as a direct critique of many of [Plaintiff's expert]'s opinions, particularly those regarding mesh contracture and degradation." ECF No. 144 at PageID #: 18313. As support, Defendants further state that Dr/ Felix's opinion is based on "(1) his knowledge of female anatomy, tissues, and TVT placement, (2) a compilation of clinical studies in meta-analysis (citing two peer-reviewed, published articles), and (3) two published studies showing no mesh contracture interfering with urine flow." Id. at PageID #: 18315.

C. Plaintiff's Motion to Exclude or Limit the General Opinions and Testimony of Salil Khandwala, M.D. ("Dr. Khandwala") (ECF No. 139)

Plaintiff seeks to exclude Dr. Khandwala's testimony because "Dr. Khandwala offers

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opinions in this case that exceed the bounds of his qualifications and are founded on insufficient facts and unreliable methodology" that "present a serious risk of confusing the issues and misleading the jury in this case." ECF No. 139 at PageID #: 16502. More specifically, Plaintiff avers that Dr. Khandwala (1) "is not a regulatory expert and has no experience drafting [instructions for use], patient brochures, or any other sort of warning labels or marketing materials for medical products" (*Id.* at PageID #: 16505 – 16508), (2) "is not a biomaterials expert, and he further conceded at his deposition that he is not a pathologist or toxicologist[,]" (*Id.* at PageID #: 16508 – 16509), and (3) "has no experience designing pelvic mesh products and was not in any way involved with [Defendants'] design process" (*Id.* at PageID #: 16509 – 16510).

In opposition, Defendants argue that the expert testimony should be admitted because Dr. Khandwala (1) based his opinion on "his review of the medical literature, published complication rates, information gleaned from medical conferences, and medical organization and FDA statements" (ECF No. 145 at PageID #: 18675 – 18677), (2) "will not be called to testify as to FDA regulations or the FDA clearance process" (Id. at PageID #: 18677 – 18678), (3) "is well qualified to testify as to the properties and characteristics of the mesh because he is an accomplished pelvic surgeon, board certified in [female pelvic medicine and reconstructive surgery], with extensive experience in implanting and revising pelvic mesh devices, investigating mesh slings in clinical trials, publishing on mesh surgeries, and training other surgeons in these procedures" (Id. at PageID #: 18678 – 18680), and (4) possesses "firsthand experience with the design of related products" (ECF No. 145 at PageID #: 18680 – 18681).

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II. Discussion

"When a witness 'is qualified as an expert by knowledge, skill, experience, training, or education,' he may give opinion testimony if his 'scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue'; his 'testimony is based on sufficient facts or data' and 'is the product of reliable principles and methods'; and he 'has reliably applied the principles and methods to the facts of the case."

**Babcock Power, Inc. v. Kapsalis, 854 F. App'x 1, 7 (6th Cir. 2021) (quoting Fed. R. Evid. 702).

"The trial court is the 'gatekeeper' of expert testimony, and thus it must exclude any opinion evidence that is unreliable and irrelevant, but it also has 'considerable leeway' in determining reliability. **Id.** (quoting **Conwood Co., L.P. v. U.S. Tobacco Co., 290 F.3d 768, 792 (6th Cir. 2002)).

"[A]s long as there is a reasonable factual basis for the expert's opinion, any objections to his testimony go to its weight and not its admissibility. **Id.** at 8.** (citing **In re Scrap Metal** Antitrust Litig., 527 F.3d 517, 529-31 (6th Cir. 2008)).

Applying Fed. R. Evid. 702, all three motions to exclude are denied because they are tantamount to a disagreement with the opposing expert's fact-based opinion. Each proffered expert has set forth proper bases for delivering expert opinion, including, but not limited to, firsthand professional experience and review of peer-reviewed research. The instant case involves a highly technical subject matter, and expert testimony will be particularly helpful to the trier of fact – the very purpose of admitting expert testimony. While parties should certainly challenge expert testimony, such a challenge is grounds for cross-examination, rather than exclusion. *KSP Invs., Inc. v. United States*, No. 1:07-CV-857, 2008 WL 182257, at *5 (N.D. Ohio Jan. 17, 2008) (ruling that defendant's expert testimony was permissible because the expert properly answered questions "by referencing the facts supported by the record and by using

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his experience as an international tax attorney to explain the likely financial analysis" relevant to the case); *Grover v. BMW of N. Am., LLC*, No. 1:19-CV-12, 2022 WL 205249, at *7 (N.D. Ohio Jan. 24, 2022) (holding that the requirements of expert testimony were satisfied because plaintiff's expert applied "his knowledge and experience to his examination of documents produced by [Defendant] regarding N63 oil consumption issues, as well as documentation concerning the specific facts concerning the subject vehicles in this case"). The Court understands a party's desire to exclude unfavorable testimony, but "juror common sense, cross-examination, argument by the party-opponent's attorneys, the testimony of the party-opponent's

own expert witnesses, and a cautionary instruction from the Court, if required, will normally assure that the jury fairly evaluates the expert's testimony." *Younglove Const.*, *LLC v. PSD*

Dev., LLC, 782 F. Supp. 2d 457, 465 (N.D. Ohio 2011) (quoting Conde v. Velsicol Chemical

Corp., 804 F.Supp. 972, 986 (S.D.Ohio 1992)).

III. Conclusion

For the reasons stated above, (1) Defendants' Motion to Exclude the Expert Testimony of Jimmy Mays, Ph.D, (ECF No. 127), (2) Plaintiff's Motion to Exclude Certain General Expert Opinions and Testimony of Juan Carlos Felix M.D. (ECF No. 138), and (3) Plaintiff's Motion to Exclude or Limit the General Opinions and Testimony of Salil Khandwala, M.D. (ECF No. 139) are each denied.

IT IS SO ORDERED.

April 8, 2022

/s/ Benita Y. Pearson

Date

Benita Y. Pearson United States District Judge

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